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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,520	11/15/2004	Olivera Josimovic-Alasevic	GULDE-0047	8275

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,520	JOSIMOVIC-ALASEVIC ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O'D

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 15, drawn to a tissue replacement structure and a kit comprising the same.

Group II, claim(s) 4, drawn to a tissue replacement structure.

Group III, claim(s) 5-8, 12, and 13, drawn to a method for the modification of a tissue lesion.

Group IV, claim(s) 9-11, drawn to a use of cultured cells as a source of various substances.

Group V, claim(s) 14, drawn to a use of a tissue replacement structure as a test system.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They are not joined by a special technical feature.

Groups I, IV, and V are drawn to a tissue replacement structure and multiple uses thereof. The structure as claimed, however, does not constitute a **special** technical feature under the guidelines of PCT Rule 13.2. The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Group I describes the tissue replacement structure and requires only that said structure be three-dimensional; have an outer region wherein cells capable of proliferation and migration are present; and comprise a growth factor. Naughton et al. (1991, U.S. Patent 5,032,508) teaches a three-dimensional cell culture system comprising dividing cells and a stromal matrix that provides growth factors (Abstract, Figure 5, and columns 6-

19). Because the composition of Group I is known in the art, it cannot be considered a special technical feature under PCT Rule 13.2.

Group II is drawn to a structure that is not the same as the structure of Groups I, IV, and V and, as such, lacks inventive unity with these Groups *a priori*. The structure of Group I may comprise additional components not recited or suggested in Group II, and the structure of Group I can be made by a method not recited or suggested in Group II.

Group III is drawn to a use of a structure that is not the same as the structure of Groups I, IV, and V and, as such, lacks inventive unity with these Groups *a priori*. The structure used in Group III may not comprise growth factors, while the structure of Group I may do so.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Additional components comprised in the tissue replacement structure: (a) an autologous cell suspension, (b) implants, and (c) growth factors, as in claim 1.

Tissue treatments: (d) electromagnetic fields, (e) mechanical stimulation and (f) ultrasound, as in claims 1 and 5.

Cell types: (g) cartilage cells, (h) bone cells, and (i) mesenchymal stem cells, as in claims 2 and 7.

Cell source: (j) embryonic and (k) non-embryonic.

Tissue replacements: (l) muscle tissue, (m) bone tissue, (n) connective tissue, (o) skin tissue, (p) fat tissue, (q) nervous tissue, (r) liver tissue, (s) endothelial tissue, (t) epithelial tissue, (u) cardiac smooth muscle tissue, as in claim 3.

Cell sources in Group II: (v) muscle, (w) connective tissue, (x) skin, (y) fat, (z) nervous tissue, (a') liver tissue, (b') endothelia, (c') epithelia, and (d') stem cells, as in claim 4.

Lesions: (e') bone lesion, (f') cartilage lesion, and (g') muscle lesion, as in claims 6 and 13.

Cell products: (h') intracellular messenger substances, (I') structural components, (j') scaffold components, and (k') matrix components, as in claim 9.

Intracellular messenger substances: (I') growth factors and (m') cytokines, as in claim 10.

Location of use: (n') *in vitro* and (o') *in vivo*, as in claims 11 and 14.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, if Group I is chosen, applicant should also choose ONE additional component from (a)-(c) above, ONE tissue treatment from (d)-(f) above, ONE cell type fro (g)-(i) above, ONE cell source from (j) and (k) above, and ONE tissue replacement from (l)-u) above. If Group II is chosen, applicant should also choose ONE cell source from (j) and (k) above and ONE cell source from (v)-(d') above. If Group III is chosen, applicant should also choose ONE cell source from (j) and (k) above, ONE cell type from (g)-(i) above, and ONE lesion from (e')-(g') above. If Group IV is chosen, applicant should also elect ONE cell source from (j) and (k) above, ONE cell product from (h')-(k') above, and ONE location of use from (n') and (o') above. If Group IV is chosen and species (h') is also chosen, applicant should also choose ONE intracellular messenger substance from (I') and (m') above. If Group V be chosen, applicant should also elect ONE cell source from (j) and (k) above and ONE location of use from (n') and (o') above. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-15.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

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SANDRA E. SAUCIER
PRIMARY EXAMINER